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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,324	03/24/2006	Yasuhiko Shiina	P29546	4957

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EXAMINER	
OGUNBIYI, OLUWATOSIN A	
ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
05/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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Office Action Summary	Application No.	Applicant(s)	
	10/573,324	SHIINA ET AL.	
	Examiner	Art Unit	
	OLUWATOSIN OGUNBIYI	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,7-10 and 15-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,7-10* is/are rejected.

7)☒ Claim(s) *15-17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 4/8/10 has been entered into the record. Claims 1, 3, 5 and 15-17 have been amended. Claims 2, 4, 6 and 11-14 have been cancelled. Claims 1, 3, 5, 7-10 and 15-17 are pending and are under examination.

Rejections Withdrawn

The rejection of claims 1-10 and 15-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter) is withdrawn in view of the amendment to the claims to delete the recitation that the subject is "free of renal disease and/or ischemic heart disease".

The rejection of claims 1-10 under 35 U.S.C. 112, first paragraph (scope of enablement) is withdrawn in view of the amendment to the claims.

The rejection of claims 2, 3, 4, 5 and 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims.

Claim Objections

Claims 15-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

New Rejections Based on Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Guild et al. WO 03/060465 A2 7/24/03 cited in IDS.

Claim 1 and dependent claims are drawn to a method of detecting or differentiating rheumatoid arthritis, comprising:

measuring the level of human lipocalin-type prostaglandin D synthase (L-PGDS) in a sample collected from a subject suspected of having rheumatoid arthritis comparing the measured level of human L-PGDS with a predetermined cut-off value based on (i) measurements of human L-PGDS in samples collected from healthy volunteers and/or patients with joint diseases other than rheumatoid arthritis, and (ii) measurements of human L-PGDS in samples collected from rheumatoid arthritis patients; and detecting or differentiating rheumatoid arthritis if the level of L-PGDS in

the sample collected from the subject suspected of having rheumatoid arthritis is higher than the predetermined cut-off value.

Claim 3 and dependent claims are drawn to a method of determining the stage of disease with regard to rheumatoid arthritis, comprising:

measuring the level of human L-PGDS in a sample collected from a subject having rheumatoid arthritis or suspected of having rheumatoid arthritis; comparing the measured level of human L-PGDS with a predetermined cut-off value based on measurements of human L-PGDS in samples collected from rheumatoid arthritis patients classified in accordance with the stage of disease; and determining the stage of disease with regard to rheumatoid arthritis, wherein L-PGDS concentration increases with advancement of the stage of disease.

Claim 5 and dependent claims are drawn to a method of determining the degree of dysfunction or severity with regard to rheumatoid arthritis, comprising:

measuring the level of human L-PGDS in a sample collected from a subject rheumatoid arthritis or suspected of having rheumatoid arthritis comparing the measured level of human L-PGDS with a predetermined cut-off value based on measurements of human L-PGDS in samples collected from rheumatoid arthritis patients classified in accordance with the degree of dysfunction or severity; and determining the degree of dysfunction or severity with regard to rheumatoid arthritis, wherein L-PGDS concentration increases with advancement of the degree of dysfunction or severity.

Guild et al teaches a method of detecting or differentiating rheumatoid arthritis comprising measuring the levels of human L-PGDS in samples collected from a subject suspected of having rheumatoid arthritis (i.e. assessing whether a patient is afflicted

with rheumatoid arthritis), comparing the measured level of human L-PGDS with a predetermined cut-off value based on (i) measurements of human L-PGDS in samples collected from healthy subjects (or patients with joint diseases other than rheumatoid arthritis) without RA or subjects with RA; and detecting or differentiating rheumatoid arthritis in the sample collected from a subject is if the level of L-PGDS is higher than the predetermined value. See p. 12 lines 26-34 and p. 13 lines 1-6 and p. 14 and p. 93 and table 1 and 2 marker M177. Guild et al (p. 13 lines 1-6) teach that population average values for expression of the human L-PGDS may be used as the "normal" such as reference ranges for the marker i.e. LPGDS in subjects with and without rheumatoid arthritis. See abstract, p. 13 lines 17-21, p. 14 lines 6-22, p. 93 and table 1 and 2 p. 108 and p. 140 respectively, marker M177. Said samples include body fluids such as blood fluids, urine, synovial/joint fluid etc. See p. 4 lines 10-16. Said level of L-PGDS is measured by immunoassay. See p. 16 lines 32-34 and p. 16 lines 6-13.

Guild et al also teaches determining the stage of disease with regard to rheumatoid arthritis or degree of dysfunction or severity with regard to rheumatoid arthritis (i.e. erosive RA versus non-erosive RA or late disease versus early disease) by comparing levels of human L-PGDS in a sample collected from a subject having rheumatoid arthritis (a patient sample) and comparing the measured level of human L-PGDS with a pre-determined cut-off value i.e. a control sample which is the level of human L-PGDS in samples collected from rheumatoid arthritis patients classified in accordance with the stage of disease (non-erosive rheumatoid arthritis) and

determining the stage of disease with regard to rheumatoid arthritis wherein the concentration of LPGDS concentration increases with advancement of the stage of disease i.e. a significant difference in level of expression of human L-PGDS in the patient sample and the control is an indication that the patient is afflicted with erosive rheumatoid arthritis. See p. 11 lines 20-31, p. 12, p. 13 lines 1-6, and p. 85 lines 20 to 32 and p. 165 claims 5-7.

Status of Claims

Claims 1, 3, 5 and 7-10 are rejected. Claims 15-17 are object to. No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can generally be reached on M-F 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Oluwatosin Ogunbiyi/
Examiner, Art Unit 1645
/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645